



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,228	11/05/2003	Michael R. Slater	341.030US1	8004

21186 7590 10/20/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/702,228

Applicant(s)

SLATER ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 13-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/1/05, 4/14/05, 9/23/05, 3/9/06, 10/28/05, 12/27/05 .

DETAILED ACTION

Claims 1-67 are pending in the case.

Receipt of Information Disclosure Statements on 8/1/05, 4/14/05, 9/23/05, 3/9/06, 10/28/05, 12/27/05 is acknowledged.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-12 in the reply filed on 8/2/06 is acknowledged. The traversal is on the ground(s) that the groups of claims are related and that therefore a search of all groups would not be burdensome. This is not found persuasive because of the reasons set forth in the election requirement, the groups of claims are drawn to separate and distinct subject matter and the search required for each group is separate and therefore a search for all groups would indeed be burdensome. Applicant has pointed to no error in the restriction requirement or in the reasons for distinctness made by the Examiner. It is further noted that the search required for biotechnology applications requires search of non-patent literature as well as patent literature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 13-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/2/06.

Claim Rejections - 35 USC § 112

Art Unit: 1636

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claims 10-12 are drawn to a vector comprising a recognition site that generates a 3'TA overhang which is 5' to a recognition site for a second enzyme that generates blunt ends, which vector when digested with said enzymes and ligated to a DNA fragment comprising an open reading frame flanked by an end generated by Sgfl and an end generated by a third restriction enzyme that has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends yields a recombinant vector comprising the open reading frame, and wherein the ligation generates particular sequences recited in claims 10-12. Claims 10-12 are genus claims in terms of vectors which when cut with restriction enzymes which generate a -TA end and a blunt end, and when ligated to fragments having ends generated by Sgfl and an enzyme which

Art Unit: 1636

has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, yields particular sequences at the ligation point. The

The claims encompass a broad class of vectors having any restriction enzyme sites that meet certain characteristics regarding frequency of occurrence and the ends produced after restriction, and the resulting sequences after ligation to DNA fragments, and many unspecified and unknown restriction sites and enzymes may be encompassed which are not described. While the specification provides general information on the nature of the sites which may be utilized, there is no disclosure of the precise structure of a representative number of restriction sites that are encompassed by the claim. One of skill in the art cannot envision all the vectors having restriction sites which will yield the claimed vector based on the teachings of the specification.

Therefore, the specification does not describe the claimed vectors having particular restriction enzyme sites in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the method at the time of filing the present application.

Thus, the written description requirement has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 are vague and indefinite since it appears that some of the recited restriction enzymes do not yield blunt ends (i.e. HindIII). Therefore it cannot be determined what the intended metes and bounds of the claim are.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bilcock et al. (J. Biol. Chem. 274, 51, 36379-36386, 1999) (cited by applicants).

Bilcock et al. disclose a vector comprising a recognition site for Sgfl, which generates a 3'TA overhang, which is 5' to a recognition site for a second restriction enzyme which generates blunt ends, i.e. an enzyme such as Sall, EcoRV, or Ball, HindIII, which may yield blunt ends (see Fig. 1, pDB8 or pDB7). The vector would, when cut digested with the first and second restriction enzymes and ligated to a DNA fragment comprising an open reading frame flanked by the ends recited in claim 1, yield a recombinant vector comprising the open reading frame. It is noted that the second phrase, i.e. that reciting the DNA fragment, does not limit or change the claimed subject matter, which is the vector comprising the first and second restriction site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/16/06


NANCY VOGEL
PRIMARY EXAMINER